

Can cervical stiffness assessment using the Pregnolia System predict the outcome of induction of labour? A feasibility, cohort study.

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Introduction

Induction of labour (IOL) is a common obstetric intervention utilised in over one third of pregnancies in England¹.

Currently no bedside test can predict success of IOL². The Bishop's Score (BS) remains the pre-induction cervical assessment of choice despite its' lack of effectiveness and subjectivity³.

The Pregnolia System is a novel, licensed, CE-marked, aspiration-based device proven to provide objective, quantitative cervical stiffness (CS) measurements (figure 1)^{4,5}.

This is the first clinical, feasibility study to take CS measurements prior to IOL.

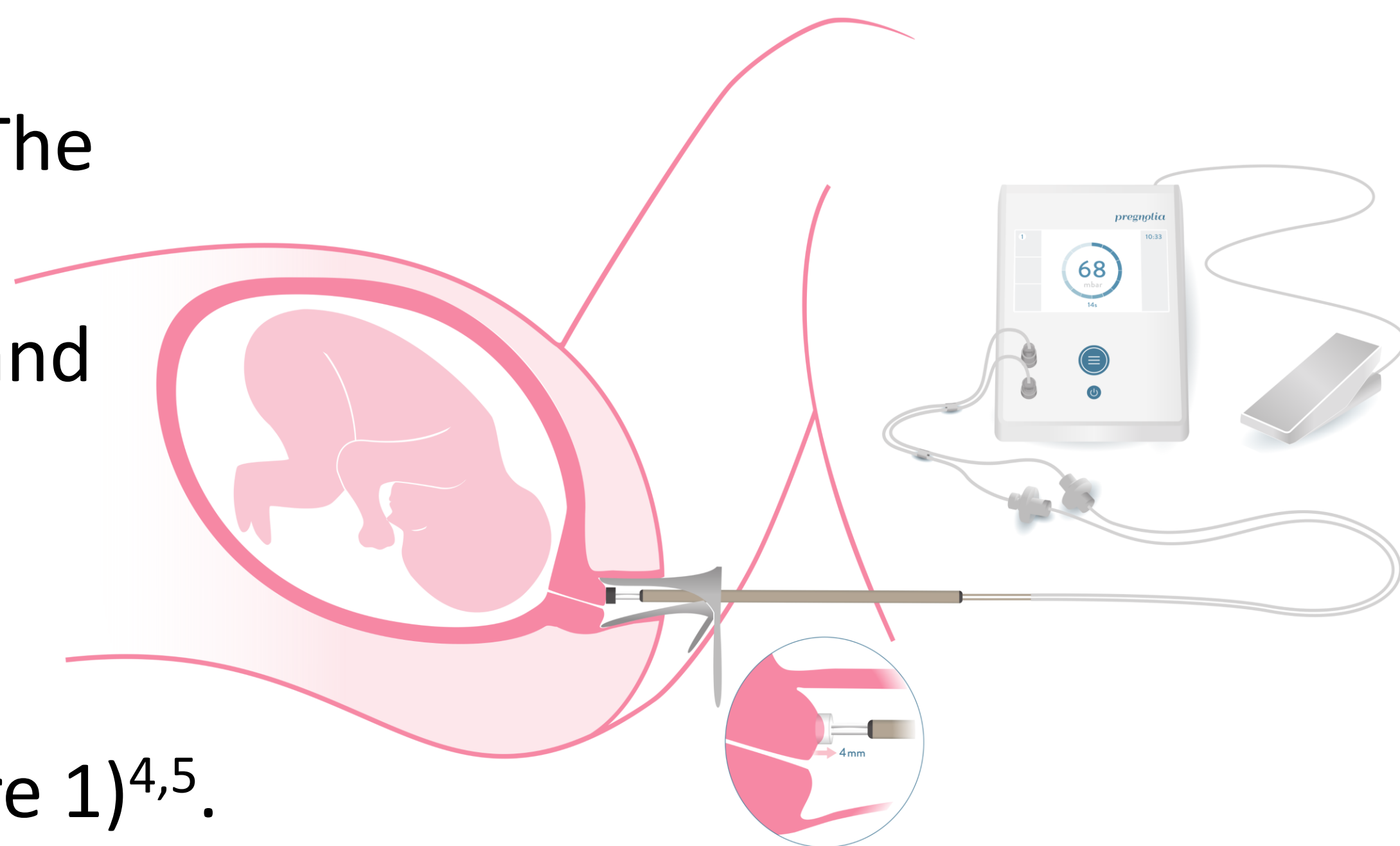


Figure 1. Pregnolia System. © Copyright 2024 Pregnolia AG. Reproduced with permission.

Results

Feasibility outcomes

GOOD Recruitment rate achieved- 68%

- 148 approached over 12 months
- 100 participants recruited

GOOD Acceptability profile

- **92%** would have repeat CS assessment
- CS mean discomfort score out of 10= **1.20**
- BS mean discomfort score out of 10= **4.93**
- Mean difference between scores **p<0.001**

GOOD Cervical stiffness measurement reliability

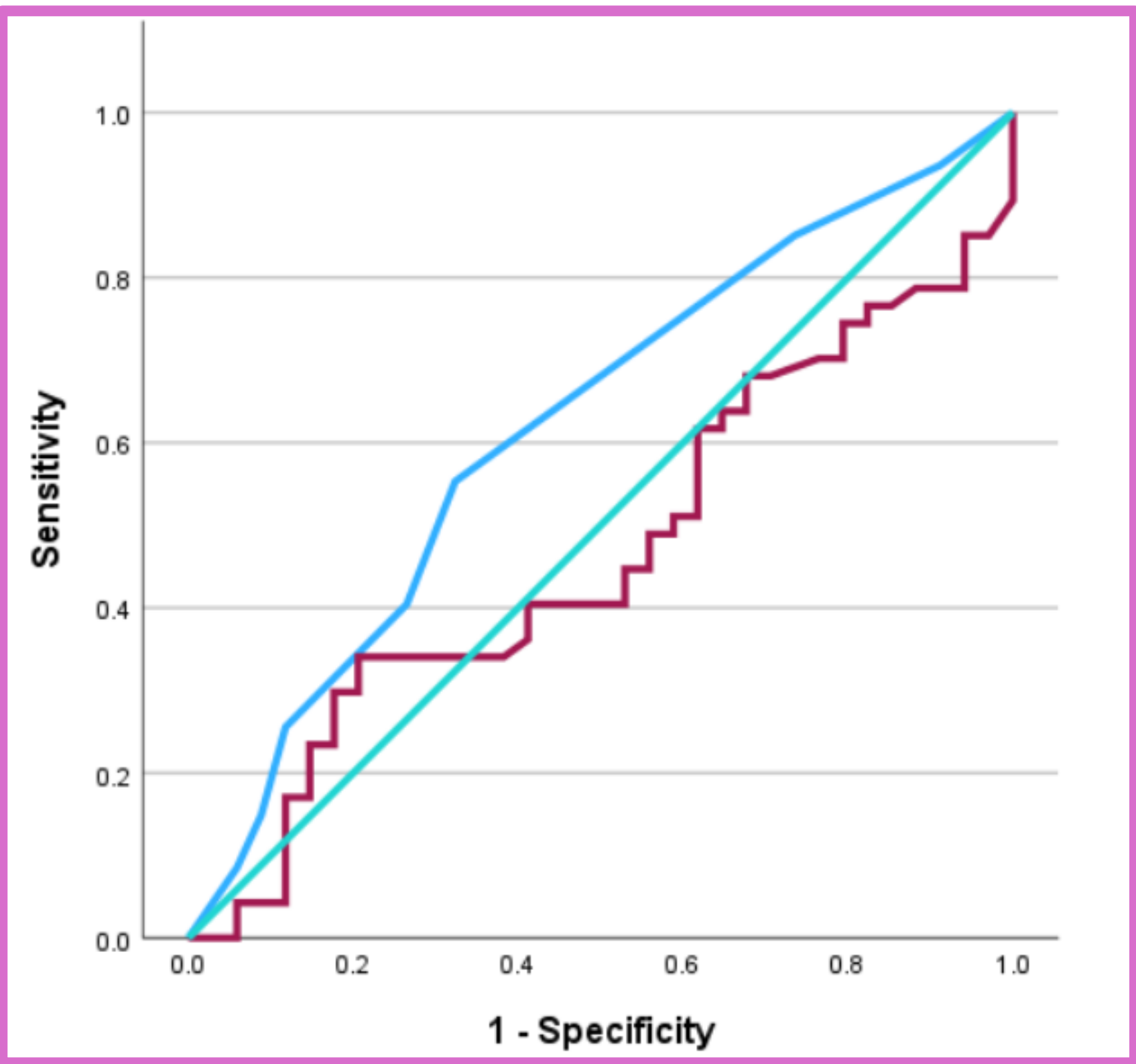
- Triplicate readings achieved in **78%**
- Excellent internal consistency- Cronbach's alpha **.967**

UNCERTAIN Clinical utility of device

- No association between cervical stiffness and clinical outcomes in preliminary data of this feasibility study.
- Requires further investigation.

Clinical outcomes

ROC Curve - Vaginal Delivery after IOL



— Bishop's Score **AUC=0.621 (95% CI 0.497, 0.745)**
— Mean Cervical Stiffness **AUC=0.466 (95% CI 0.340, 0.593)**
— Reference Line

Study Design Single site, prospective, feasibility study. Recruitment at time of attendance for booked IOL.

Methods

Eligibility

Study procedures

Outcomes

- Primiparous
 - Membranes intact
 - ≥37+0 weeks
 - Booked for IOL at LWH
- Pre-induction;
- Cervical stiffness assessment
 - Bishop's score assessment
 - Participant questionnaire
- Outcomes
- Feasibility collected at study visit
 - Clinical collected after delivery

Aims

- 1) Explore acceptability of the Pregnolia System for CS assessment in this population
- 2) Determine reliability of triplicate CS measurements in this cohort
- 3) Explore potential association between CS and vaginal delivery following IOL and compare to BS taken concurrently
- 4) Inform for design of appropriately powered study using the Pregnolia System for IOL prediction

Discussion

Use of the Pregnolia System for pre-induction cervical assessment is feasible with good recruitment achievable with reliable CS measurements obtained. Importantly this novel assessment is acceptable in this population and scored more favourably than routine BS assessment.

However, in this feasibility study the clinical utility of the device for correlation with delivery outcome following IOL could not be demonstrated and did not improve upon current standard practice of BS assessment.

Further studies on a more homogeneous population and under controlled settings are required to conclude on the value of this device in IOL.

References

1. NHS Maternity Statistics 2022-23.
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3. Kolkman DG et al. PubMed PMID: 23283806
4. Badir S et al. PubMed PMID: 23274486.
5. Badir S et al. PubMed PMID: 32631265